MEDICAL INFUSION PUMP WITH CLOSED LOOP STROKE FEEDBACK SYSTEM AND METHOD

BACKGROUND OF THE INVENTION

5   The present invention relates to a means of determining and controlling the operating condition of a medical pump. More particularly, this invention relates to a means of adjusting a stroke frequency of a pump to compensate for individual variation in the stroke volume delivered by the

10 medical pump.

    Modern medical care often involves the use of medical pump devices to deliver fluids and/or fluid medicine to patients. Medical pumps permit the controlled delivery of fluids to a patient, and such pumps have largely replaced

15 gravity flow systems, primarily due to the pump's much greater accuracy in delivery rates and dosages, and due to the possibility for flexible yet controlled delivery schedules. Of the modern medical pumps, those incorporating a diaphragm are often preferred because they provide a more accurate

20 controlled rate and volume than do other types of pumps.

    A typical positive displacement pump system includes a pump device driver and a disposable fluid or pumping chamber, defined in various forms including but not limited to a cassette, syringe barrel or section of tubing. A disposable

25 cassette, which is adapted to be used only for a single patient and for one fluid delivery cycle, is typically a small plastic unit having an inlet and an outlet respectively connected through flexible tubing to the fluid supply container and to the patient receiving the fluid. The

30 cassette includes a pumping chamber, with the flow of fluid through the chamber being controlled by a plunger or pumping element activated in a controlled manner by the device driver.

    For example, the cassette chamber may have one wall

formed by a flexible diaphragm that is reciprocated by the plunger and the driver to cause fluid to flow. The pump driver device includes the plunger or pumping element for controlling the flow of fluid into and out of the pumping

5   chamber in the cassette, and it also includes control mechanisms to assure that the fluid is delivered to the patient at a pre-set rate, in a pre-determined manner, and only for a particular pre-selected time or total dosage.

The fluid enters the cassette through an inlet and is

10 forced through an outlet under pressure. The fluid is delivered to the outlet when the pump plunger forces the membrane into the pumping chamber to displace the fluid. During the intake stroke the pump plunger draws back, the membrane covering the pumping chamber pulls back from its

15 prior fully displaced configuration, and the fluid is then drawn through the open inlet and into the pumping chamber. In a pumping stroke, the pump plunger forces the membrane back into the pumping chamber to force the fluid contained therein through the outlet. Thus, the fluid flows from the cassette

20 in a series of spaced-apart pulses rather than in a continuous flow.

One of the requirements for a medical pump is that it is able to deliver precise volumes at precise delivery rates. Conventional pumps, in general, rely on nominal or empirical

25 data to estimate the delivery volumes and delivery rates, and do not provide mechanisms for adjusting an actual delivery due to variations from this nominal or empirical data. This lack of adjustment during an actual delivery limits the accuracy of these pumps.

30 It is therefore a principal object of this invention to provide means for adjusting a stroke frequency of the pump to compensate for variation in the stroke volume based on pressure data from the medical pump.

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These and other objects will be apparent to those skilled in the art.

SUMMARY OF THE INVENTION

5   A medical pump with a closed loop stroke feedback system and method, for use with a fluid chamber or pumping chamber, is disclosed. The fluid or pumping chamber can be included in or defined by a cassette, syringe barrel, or section of tubing. The pump includes a pumping element that

10 intermittently pressurizes the pumping chamber during a pumping cycle. A pressure sensor detects the pressure exerted by the pumping element on the pumping chamber. A position sensor detects the position of the pumping element. A processing unit processes pressure data from the pressure

15 sensor and position data from the position sensor to determine a calculated stroke volume of the pump for a pump cycle, and to adjust a stroke frequency of the pump to compensate for variation in the stroke volume.

    In operation, the processing unit sets a stroke frequency

20 for a desired dosage rate based on a nominal stroke volume, determines when an outlet valve of the pumping chamber opens, determines a calculated pressurization volume from a beginning of the pump cycle to the point when the outlet valve opens, determines a change in pressurization volume by subtracting

25 the calculated pressurization volume from a nominal pressurization volume, determines a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber expansion under pressure at the middle of the pumping cycle to pumping chamber expansion under pressure at

30 the start of the pumping cycle, determines a calculated stroke volume based on the change in stroke volume, and adjusts the stroke frequency to compensate for variation between the calculated stroke volume and the nominal stroke volume.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of one embodiment of a medical pump according to the present invention;

FIG. 2 is schematic diagram of an alternative embodiment of a medical pump according to the present invention;

FIG. 3 is schematic diagram of another alternative embodiment of a medical pump according to the present invention;

FIG. 4 is schematic diagram of another alternative embodiment of a medical pump according to the present invention;

FIG. 5 is a perspective view of a cassette, which can be used as the pumping chamber in accordance with one embodiment of the present invention;

FIGS. 6-9 are cross sectional views of the pumping element of the present invention driving a cassette through a pumping cycle;

FIG. 10 is a graph plotting force data versus the pump plunger position from a pump cycle;

FIG. 11 is a flow chart illustrating one embodiment of determining and adjusting the operating condition of a medical pump according to the present invention;

FIG. 12 is a flow chart illustrating a further embodiment of determining and adjusting the operating condition of a medical pump according to the present invention; and

FIG. 13 is a graph of twenty second incremental bolus volume versus time using the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to FIG. 1, the functional components of one embodiment of a medical pump 10 are shown in schematic form. The medical pump 10 is used in connection with a

disposable fluid chamber, such as a cassette 12 for delivering a fluid to a patient. As will be described below in greater detail the medical pump 10 of the present invention provides a mechanism for adjusting an actual delivery of fluid based on

5   variations from nominal data used to estimate pump performance. It will be understood to one of ordinary skill in the art that the term medical pump as used herein includes but is not limited to enteral pumps, infusion pumps, cassette pumps, syringe pumps, peristaltic pumps, or any positive

10   displacement fluid pumping device for the delivery of fluids intravenously or intra-arterially to a patient.

The medical pump 10 and cassette 12 are shown with several components for implementing the present invention. Those of ordinary skill in the art will appreciate that the

15   pump 10 and cassette 12 may include many more components than those shown in FIG. 1. However, it is not necessary that all these components be shown in order to disclose an illustrative embodiment for practicing the present invention.

With reference to FIG. 5, one cassette 12 suitable for

20   use with the present invention is shown. It will be understood to one of ordinary skill in the art that a cassette or fluid chamber having a different design than that shown in FIG. 5 may be used with pump 10 without departing from the present invention.

25   The cassette 12 may include an inlet 14 and an outlet 16 formed in main body 18. An inlet fluid line 20 couples the inlet port 14 on the main body 18 to a fluid source (not shown) such as an IV bag or other fluid container. Similarly, an outlet fluid line 22 couples the outlet port 16 on main

30   body 18 to the body of a patient (not shown).

With reference to FIG. 6, a resilient elastomeric membrane or diaphragm 23 forms a pumping chamber 24, inlet valve 26, and outlet valve 28 on an inner face 68 of the main

body 18. The pumping chamber 24 is connected in fluid flow communication between the inlet port 14 and the outlet port 16. The pumping chamber 24 operates to meter fluid through the cassette 12.

5   The inlet valve 26 resides between inlet port 14 and the pumping chamber 24. Inlet valve 26 operates to physically open and close the fluid communication between inlet port 14 and pumping chamber 24.

        Similarly, the outlet valve 28 resides between the

10   pumping chamber 24 and outlet port 16. Outlet valve 28 operates to physically open and close the fluid communication between pumping chamber 24 and outlet port 16. The pumping chamber 24, inlet valve 26, and outlet valve 28 are all operatively associated with the pump 10 to control the flow of

15   fluid through the cassette 12. As will be understood from the description below, the cassette is a passive valve system requiring pressurization of the pumping chamber 24 prior to fluid delivery. Inlet valve 26 and outlet valve 28 react to the pressure of the pumping element 44 on the pumping chamber

20   24.

        In operation, fluid enters through the inlet 14 and is forced through outlet 16 under pressure. The fluid is delivered to the outlet 16 when the pump 10 displaces the membrane 23 and thereby compresses the pumping chamber 24 to

25   expel the fluid. As shown in FIG. 6, the pumping cycle begins with the pumping chamber 24 in a non-compressed position. As shown in FIG. 7, as the pump 10 begins to displace the membrane 23 on the pumping chamber 24, the pumping chamber 24 is compressed while the outlet valve 28 remains closed. As

30   shown in FIG. 8, once the pump 10 displaces the membrane 23 on the pumping chamber 24 to a given extent, the outlet valve 28 opens and fluid flows to the outlet 16. As shown in FIG. 9, during the intake stroke the pump 10 releases the resilient

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membrane 23 over the pumping chamber 24, and the fluid is then
drawn through the inlet 14 and into the pumping chamber 24
once inlet valve 26 opens. Thus, the fluid flows from the
cassette 12 in a series of spaced-apart pulses rather than in
5   a continuous flow. The fluid is delivered to the patient at a
pre-set rate, in a pre-determined manner, and only for a
particular pre-selected time or total dosage.

Referring to FIG. 1, a processing unit 30 is included in
pump 10 and performs various operations described in greater
10   detail below. An input/output device 32 communicates with the
processing unit 30 and allows the user to receive output from
processing unit 30 and/or input information or commands into
the processing unit 30. Those of ordinary skill in the art
will appreciate that input/output device 32 may be provided as
15   a separate display device and a separate input device.

A memory 34 communicates with the processing unit 30 and
stores code and data necessary for the processing unit 30 to
calculate and output the operating conditions of pump 10.
More specifically, the memory 34 stores a programming code 36
20   formed in accordance with the present invention for processing
data to determine and control the operating condition of the
pump 10.

A clock 37 is used to keep time in the pump 10. The
clock 37 is connected to the processing unit 30, and provides
25   the processing unit 30 with time information for correlating
data over time or conducting time sensitive activities.

An electric motor 38 is controlled by processing unit 30
and is energized by a power supply 40 to serve as a prime
mover for rotatably driving a shaft 42 connected to the motor
30   38. The processing unit 30 orders the motor 38 to run at
different speeds depending on the flow rate desired through
the pump 10. The down-stroke or delivery portion of the
stroke has the motor 38 running directly from power supply 40.

The up-stroke, retract or fill portion of the stroke is run at a voltage set by the processing unit 30, so that the retract times are varied by the processing unit 30, where higher desired flow rates require faster retract speeds.

5   A pumping element 44 is operatively associated with the shaft 42. When energized, the pumping element 44 reciprocates back and forth to periodically down-stroke, causing pumping element 44 to press on pumping chamber 24, and expel fluid therefrom. On an up-stroke, pumping element 44 releases

10 pressure from pumping chamber 24 and thereby draws fluid from inlet port 16 into pumping chamber 24. Thus, the pumping element 44 intermittently pressurizes the pumping chamber 24 during a pumping cycle.

      A pressure sensor 46 is operatively associated with the

15 pumping element 44 to detect the force or pressure exerted by the pumping element 44 on the pumping chamber 24. As shown, the pressure sensor 46 is directly connected to the pumping element and is positioned in-line with the pumping element 44, between the pumping chamber 24 and the shaft 42. The pressure

20 sensor 46 is the only pressure sensor included in the medical pump 10, and operates to sense the force on pumping element 44 as well as to generate a pressure signal based on this force. The pressure sensor 46 is in electronic communication with the processing unit 30 to send the pressure signal to the

25 processing unit 30 for use in determining operating conditions of pump 10. One of ordinary skill in the art will appreciate that the pressure sensor 46 may be a force transducer or any other device that can operatively sense the pressure brought to bear on the pumping chamber 24 by pumping element 44.

30   A position sensor 48 is operatively associated with the pumping element 44 to directly or indirectly detect the position of the pumping element 44. The position sensor 48 tracks the pumping cycle of pump 10 by detecting the position

of the pumping element 44. As shown, the position sensor 48
is associated with the shaft 42. The position sensor 48
generates a position signal by detecting the rotational
position of the shaft 42. The position sensor 48 is in
5   electronic communication with the processing unit 30 to send
the position signal to the processing unit 30. The processing
unit 30 utilizes this information to associate the incoming
pressure data with a particular portion of the pump cycle.
One of ordinary skill in the art will appreciate that the
10   position sensor 48 could alternatively track a cam attached to
the shaft 42 or the pumping element 44. Additionally, one of
ordinary skill in the art will appreciate that the position
sensor 48 as used herein includes but is not limited to
mechanical indicators such as pivoting dial indicators,
15   electronic switches, Hall Effect sensors, and optical based
position detectors.

Referring to FIG. 2, an alternative embodiment of the
medical pump 10 is shown. In this embodiment the pressure
sensor 46 comprises a current signal from the motor 38. The
20   current signal from the motor 38 is proportional to the force
exerted on the pumping chamber 24 through the pumping element
44 by the motor 38. As is also the case in FIG. 1, the
pressure sensor 46 is the only pressure sensor included in the
medical pump 10, and operates to sense the force on pumping
25   element 44 as well as to generate a pressure signal to the
processing unit 30 based on this force.

Referring to FIG. 3, another alternative embodiment of
the medical pump 10 is shown. In this embodiment the pressure
sensor 46 comprises a strain gauge directly connected to the
30   pumping chamber 24 of the cassette 12. The current signal
from the strain gauge is proportional to the force exerted on
the pumping chamber 24 by the pumping element 44. As is also
the case in FIG. 1, the pressure sensor 46 is the only

pressure sensor included in the medical pump 10, and operates to sense the force on pumping element 44 as well as to generate a pressure signal to the processing unit 30 based on this force.

5   Referring to FIG. 4, yet another alternative embodiment of the medical pump 10 is shown. In this embodiment the pressure sensor 46 comprises a pressure probe located at least partially within the pumping chamber 24 of the cassette 12. The current signal from pressure probe is proportional to the

10   force exerted on the pumping chamber 24 by the pumping element 44. As is also the case in FIG. 1, the pressure sensor 46 is the only pressure sensor included in the medical pump 10, and operates to sense the force on pumping element 44 as well as to generate a pressure signal to the processing unit 30 based

15   on this force.

        Referring to FIG. 10, an exemplary force curve is shown where the pumping element 44 applies force p_i (shown in psi units) to the pumping chamber 24 while moving in essentially a constant cyclic (sine-wave) motion through 360 degrees θ_i

20   (shown in units of degrees) of rotation per cycle. The pumping element 44 always has sufficient force available from the motor 38 so that its speed is essentially independent of the force p_i applied to the pumping element 44, and the outlet flow from pumping chamber 24 is not restricted.

25   The curve starts at 0 degrees or Bottom Dead Center (BDC) with the pumping element 44 deflecting the diaphragm 23 of the pumping chamber 24 a minimal amount at this point. The position of the pumping element 44 at 0 degrees, and the resultant displacement of pumping chamber 24 can be seen in

30   FIG. 6.

        Cycle portion A shows the pressurization of the pumping chamber 24 and is shown in this example as occurring from 0 to 30 degrees. During the pressurization cycle portion A, the

pumping element 44 moves into the cassette 12 (which is called the pressurization stroke because fluid is compressed in pumping chamber 24 of the cassette 12) building force within the pumping chamber 24, while the outlet valve 28 remains

5   closed. The position of the pumping element 44 between 0 and 30 degrees, and the resultant displacement of pumping chamber 24 can be seen in FIG. 7.

A delivery cycle portion B begins when the force within the pumping chamber 24 is sufficient to open the outlet valve

10   28. During the delivery cycle portion B, the pumping element 44 moves into the cassette 12 so as to build a force within the pumping chamber 24 sufficient to open the outlet valve 28 and expel fluids from the pumping chamber 24. The delivery cycle portion B is shown in this example as occurring from 30

15   to 180 degrees. The position of the pumping element 44 between 30 and 180 degrees, and the resultant opening of the outlet valve 28 can be seen in FIG. 8.

The delivery cycle portion B ends at Top Dead Center (TDC), or 180 degrees of rotation, and a depressurization

20   cycle portion C begins. The depressurization cycle portion C shows the depressurization the pumping chamber 24 and is shown in this example as occurring from 180 to 210 degrees. During the depressurization cycle portion C, the pumping element 44 moves out of the cassette 12 (which is called the up-stroke,

25   depressurization or inlet stroke) and the force drops off. As the diaphragm 23 returns to its initial position, while the inlet valve 26 remains closed, negative pressure builds within the pumping chamber 24.

A refill cycle portion D begins when the negative

30   pressure within the pumping chamber 24 is sufficient to the open the inlet valve 26. During the refill cycle portion D, the pumping element 44 moves out the cassette 12 building negative pressure within the pumping chamber 24 sufficient to

open the inlet valve 26 and draw fluids into the pumping chamber 24. The refill cycle portion D is shown in this example as occurring from 210 to 360 degrees, or Bottom Dead Center (BDC). The position of the pumping element 44 between

5   210 to 360 degrees, and the resultant opening of the inlet valve 26 can be seen in FIG. 9.

Referring to FIGS. 1 and 11, the pump 10 of the present invention provides a mechanism for controlling or adjusting an actual delivery of fluid based on variations from nominal data

10   used to estimate pump performance. The processing unit 30 retrieves the operating condition programming code 36 from memory 34 and applies it to the pressure and position data received during this pump cycle. The pump pressure data and pump position data are processed by the processing unit 30.

15   Sensing the force that the resilient diaphragm 23 of the pumping chamber 24 exerts against the pumping element 44 and analyzing that force can determine an estimated volume of fluid flow per stroke (calculated stroke volume). The processing unit 30 utilizes the calculated stroke volume in a

20   closed loop stoke feedback system to modify the stroke frequency to compensate for variation in the stroke volume. In the closed loop stroke feedback system, the processing unit 30 adjusts an actual delivery of fluid based on variation between the calculated stroke volume and nominal data used to

25   estimate pump performance.

Specifically, the processing unit 30 begins execution of the programming code 36 at a block 50 and proceeds to block 52 where the processing unit 30 sets a stroke frequency for a desired dosage rate. The stroke frequency is determined by

30   the processing unit 30 based on a nominal stroke volume. This nominal stroke volume can be supplied from empirical evidence of an average normal stroke volume for all pumps of a particular type or for each individual pump. Once the stroke

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frequency is set, the processing unit 30 proceeds to block 54 where it determines a calculated stroke volume of the pump for a pump cycle based on the pressure data from the pressure sensor 46 and position data from the position sensor 48. Once

5   the calculated stroke volume has been determined, the processing unit 30 proceeds to decision block 56 where it determines if the calculated stroke volume is greater than a given threshold value. One of ordinary skill in the art will understand that the threshold value disclosed herein is

10   predetermined from experimental data, and will vary from pump model to pump model.

If the result from decision block 56 is negative, then the execution of the programming code 36 by the processing unit 30 is complete and ends in block 60. If the result from

15   decision block 56 is positive, then the processing unit 30 proceeds to block 58 where it adjusts the stroke frequency to compensate for the variation between the calculated stroke volume and the nominal stroke volume. Once the stroke frequency has been adjusted, the execution of the programming

20   code 36 by the processing unit 30 is complete and ends in block 60.

Referring to FIGS. 1, 10 and 12, a further embodiment of determining the operating condition of a medical pump according to the present invention is shown. Like the

25   embodiment shown in FIG. 11, in the present embodiment, the processing unit 30 retrieves the operating condition programming code 36 from memory 34 and applies it to the pressure and position data received during this pump cycle. The pump pressure data and pump position data are processed by

30   the processing unit 30. Sensing the force that the diaphragm 23 of the pumping chamber 24 exerts against the pumping element 44 and analyzing that force can determine an estimated volume of fluid flow per stroke (calculated stroke volume).

The processing unit 30 utilizes the calculated stroke volume in a closed loop stroke feedback system to modify the stroke frequency to compensate for variation in the stroke volume. In the closed loop stroke feedback system, the processing unit

5   30 adjusts an actual delivery of fluid based on variation between the calculated stroke volume and nominal data used to estimate pump performance.

Specifically, the processing unit 30 begins execution of the programming code 36 at a block 62 and proceeds to block 64

10   where the processing unit 30 sets a stroke frequency for a desired dosage rate. Like step 52 from FIG. 10, the stroke frequency is determined by the processing unit 30 based on a nominal stroke volume.

Once the stroke frequency is set, the processing unit 30

15   proceeds to block 66 where the processing unit 30 determines when an outlet valve 28 of the pumping chamber opens. The processing unit 30 determines the opening of outlet valve 28 based on data from the pressurization cycle portion A (as shown in FIG. 10). During the pressurization cycle portion A

20   pumping element 44 moves into the cassette 12 building force within the pumping chamber 24 to a point where the outlet valve 28 opens.

Specifically, by monitoring the slope of the pressure data over time, the opening of the outlet valve 28 can be

25   determined. For instance, by taking the derivative of the pressure data over time, where the pressure derivate is greater than zero in the following equation:

$$\frac{dp}{dt} \vartriangleright 0$$

the pressure within the pumping chamber 24 is increasing and

30   the outlet valve 28 remains closed. Where the pressure derivate is less than zero in the following equation:

$$\frac{dp}{dt} \triangleleft 0$$

the pressure within the pumping chamber 24 is decreasing and the outlet valve 28 has opened, and the processing unit 30 determines at what angular position the pumping element 44 was

5   in when the outlet valve 28 opened (i.e., where dp/dt changes from > 0 to < 0).

Once the outlet valve 28 opening is determined, the processing unit 30 proceeds to block 68 where the processing unit 30 determines a calculated pressurization volume from the

10 beginning of the pump cycle to the point when the outlet valve opens. The processing unit 30 determines the calculated pressurization volume based on data from the pressurization cycle portion A (as shown in FIG. 10). During the pressurization cycle portion A pumping element 44 moves into

15 the cassette 12 building force within the pumping chamber 24, while the outlet valve 28 remains closed.

Specifically, the processing unit 30 converts the angle at which the outlet valve 28 opens to a displacement distance of the pumping element 44 as follows:

$$x_i = L_{cam} * (1 - \cos(\theta_i))$$

20 where x_i is the displacement distance, L_{cam} is half the distance of a stroke for the pumping element 44, and θ_i is the angular position of the pumping element 44 at which the outlet valve 28 opened. The processing unit 30 converts the displacement

25 distance x_i into a pressurization stroke volume based on a ratio of volume to displacement distance for the pump 10. This ratio is based on a nominal pressurization volume and a nominal displacement distance for a typical pump 10. This pressurization volume and a nominal displacement distance can

30 be supplied from empirical evidence of an average normal

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stroke volume for all pumps of a particular type or for each individual pump.

Once the calculated pressurization volume is determined, the processing unit 30 proceeds to block 70 where the

5   processing unit 30 determines a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume. Again, the nominal pressurization volume can be supplied from empirical evidence of an average normal stroke volume for all pumps of a

10   particular type or for each individual pump.

The change in pressurization volume determined here is proportional to variations in the actual stroke volume, as a portion of compressive forces can be lost and not translated into fluid delivery. For instance, a portion of compressive

15   forces can be lost where there is excessive compliance within mechanical components (such as the cassette 12) or air bubble entrained within the pumping chamber 24.

Once the change in pressurization volume is determined, the processing unit 30 proceeds to block 72 where the

20   processing unit 30 determines a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber expansion under pressure at the middle of the pumping cycle to pumping chamber expansion under pressure at the start of the pumping cycle. This "pumping chamber

25   expansion under pressure" is also referred to as the compliance of the pumping chamber. For instance, the diaphragm 23 of the cassette 12 is constructed of various materials with corresponding spring rates. As pressure is placed on the pumping chamber 24, the volume of the chamber 24

30   changes according to the overall spring rate of the cassette 12. As the volume of the pumping chamber 24 will grow larger as pressure increases. However, the pumping chamber compliance is not the same throughout the pumping cycle. At

the beginning of the pumping cycle (0 degrees) the compliance (ratio of volume change to pressure) is higher than the compliance at the middle of the pumping cycle (180 degrees). Again, the compliance can be supplied from empirical evidence

5 of an average normal stroke volume for all pumps of a particular type or for each individual pump. Thus, to better estimate the change in stroke volume, the change in pressurization volume is multiplied by a ratio of compliance at the middle of the pumping cycle to the compliance at the

10 beginning of the pumping cycle.

Once the change in stroke volume is determined, the processing unit 30 proceeds to block 74 where the processing unit 30 determines a calculated stroke volume based on the change in stroke volume. Specifically, the change in stroke

15 volume is added to the nominal stroke volume to arrive at the calculated stroke volume. This calculated stroke volume provides a very close estimate of the actual individual stroke volume delivered.

Once the calculated stroke volume has been determined,

20 the processing unit 30 proceeds to decision block 76 where it determines if the calculated stroke volume is greater than a given threshold value. One of ordinary skill in the art will understand that the threshold value disclosed herein is predetermined from experimental data, and will vary from pump

25 model to pump model. If the result from decision block 76 is negative, then the execution of the programming code 36 by the processing unit 30 is complete and ends in block 80.

If the result from decision block 76 is positive, then the processing unit 30 proceeds to block 78 where it adjusts

30 the stroke frequency to compensate for the variation between the calculated stroke volume and the nominal stroke volume. Once the stroke frequency has been adjusted, the execution of the programming code 36 by the processing unit 30 is complete

and ends in block 80.

It will be understood that the threshold determination above from block 76, could be made on criterional information other than the calculated stroke volume above. For instance,

5 the threshold determination 76 could similarly be made based on the angle at which the outlet valve 28 opens, the calculated pressure volume, the change in pressurization volume, or the change in stroke volume determined above. In any of these cases, the given threshold value would

10 necessarily be scaled according to the designated alternative criterional information. Additionally, the timing of the threshold determination 76 could also be adjusted based on the designated alternative criterional information. For instance, were the calculated pressurization volume designated as the

15 alternative criterional information, the threshold determination 76 could occur at any point after step 68.

Likewise, it will be understood that the stroke frequency adjustment above from block 78, could be made on criterional information other than the calculated stroke volume above.

20 For instance, the stroke frequency adjustment 78 could similarly be made based on the angle at which the outlet valve 28 opens, the calculated pressure volume, the change in pressurization volume, or the change in stroke volume determined above. In any of these cases, the stroke frequency

25 adjustment 78 would necessarily be scaled according to the designated alternative criterional information. Additionally, the timing of the stroke frequency adjustment 78 could also be adjusted based on the designated alternative criterional information. For instance, were the calculated pressurization

30 volume designated as the alternative criterional information, the stroke frequency adjustment 78 could occur at any point after step 68.

Additionally, further restrictions can be placed on the

execution of the stroke frequency adjustment 78 step. For
example, the calculated stroke volume could comprise multiple
calculated stroke volumes averaged together. This averaging
of multiple calculated stroke volumes potentially reduces the
5   effects that minor variations in stroke volume and/or
statistical noise have to the overall pump 10 operation.

In operation, the above closed loop stoke feedback system
embodiments provide several advantages. The first advantage
is that the actual volume delivered per stroke can be used by
10   the processing unit 30 to continuously adjust the stroke rate.
The second advantage is that the detection of the pressure
data profile and the determination of the opening of outlet
valve 28 permits the processing unit 30 to determine lost
stroke volume (i.e. calculated stroke volume as compared with
15   the nominal stroke volume) and to use this as an indicator of
presence of air in the pumping chamber 24, as well as
determining the size of air bubbles in the set. These
advantages of the present invention limit the effects of all
causes of delivery error, including: compliance of physical
20   components, air in the delivery fluid, variations in line
pressure, and manufacturing variability of physical components
(for example, in valve opening pressures).

In cassette type pumps the present invention is
particularly advantageous. As the cassettes are disposable,
25   the cassettes are produced in very high volumes there are
limitations to reducing the manufacturing variability of the
physical components and assemblies. The overall accuracy
provided by present invention improves the ability to perform
accurate deliveries within a broader range of these
30   manufacturing variabilities of the physical components and
assemblies.

The third advantage is that the detection of the pressure
data profile and the determination of the opening of outlet

valve 28 permits the processing unit 30 to deliver in smaller
increments for very low flow rates in a more continuous manner
(known as Low Flow Continuity). In general, Low Flow
Continuity is defined as the ability of a pump to deliver at
5   rates of 1 ml/hr to 0.1 ml/hr or less with periods of "no-
flow" not exceeding 20 seconds and bolus volumes not exceeding
2 micro-liters. To meet the highest Emergency Care Research
Institute (ECRI) industry standards for Low Flow Continuity
and achieve an "Excellent" ECRI rating, the pump must deliver
10   fluid in increments no greater than two micro-liters at a flow
rate of 0.1 milliliter per hour with a maximum "no-flow"
period of 20 seconds.

        As shown in FIG. 13, the present invention provides means
for reciprocating a plunger mechanism 44 of a medical pump 10
15   to deliver fluid in smaller increments for very low flow rates
in a more continuous manner sufficient to meet and exceed the
above ECRI standards. Specifically, FIG. 13 displays a pump
delivering fluid with a low flow continuity of about 1 ml/hr
or less, more specifically about 0.1 ml/hr or less, with
20   twenty second incremental bolus volumes of less than 2 µl
using the present invention. Advantageously, the same pump is
also programmable to deliver up to 1000 ml/hr.

        Whereas the invention has been shown and described in
connection with the embodiments thereof, it will be understood
25   that many modifications, substitutions, and additions may be
made which are within the intended broad scope of the
following claims. From the foregoing, it can be seen that the
present invention accomplishes at least all of the stated
objectives.

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